

Message Text

UNCLASSIFIED

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15

ORIGIN HEW-08

INFO OCT-01 EUR-25 EA-11 ISO-00 SCI-06 EB-11 RSC-01

(ISO) R

66611

DRAFTED BY: DHEW/FDA:LRSHELTON

APPROVED BY: SCI:MSBEAUBIEN

DHEW/OIH:MACODDING

EUR/CE:LHEICHLER (INFO)

EUR/WE:GHSHEINBAUM (INFO)

EA/J:RDANKERT (INFO)

EB/OT/STA:LCOHEN

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R 282143Z FEB 74

FM SECSTATE WASHDC

TO AMEMBASSY BONN

AMEMBASSY THE HAGUE

AMEMBASSY TOKYO

UNCLAS STATE 040530

E.O. 11652: N/A

TAGS: TBIO; GW; NL; JA

SUBJ: RECALL OF INTRAVENOUS CATHETER PRODUCTS

REF: STATE 037128

1. FDA ADVISES THAT VITAL ASSISTS, INC., SALT LAKE CITY, UTAH INITIATED A SUB-RECALL OF ITS HEMODIALYSIS CATHETERS ON 2/14/74. DESERET PHARM. CO., SANDY, UTAH MANUFACTURERS, PACKAGES, AND STERILIZES SINGLE NEEDLE HEMODIALYSIS CATHETERS FOR VITAL ASSISTS, INC.

2. ITEMS BEING RECALLED BY VITAL ASSISTS:
UNIPUNCTURE CATHETER, CAT. NO. K21, 14 GA. X 1 IN.
UNIPUNCTURE CATHETER, CAT. NO. K22, 14 GA. X 1-1/2 IN.
UNIPUNCTURE CATHETER, CAT. NO. K23, 16 GA. X 1 IN.
THESE ARE SINGLE NEEDLE CATHETERS FOR WHICH THERE ARE NO SUBSTITUTES
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AVAILABLE.

3. FIRM IS NOT ASKING HOSPITALS AND CLINICS TO NOTIFY PATIENTS WITH HOME DIALYSIS UNITS AT THIS TIME.

4. FOREIGN CONSIGNEES ARE:

GERMANY

FRESENIUS PHARMA, 638 BAD HOMBURG V.D.H., POSTFACH 1480,
GLUCKENSTEINWEG 5

NETHERLANDS

HILEKES B.V., POSTBOX 202 - BUSSUM

JAPAN

NIKKISO CO., LTD., 43-2 EBISU 3-CHOME, SHIBUYA-KU - TOKYO

5. POSTS REQUESTED TO ADVISE CONSIGNEES AND/OR HOST GOVERNMENT
CONTROL OFFICIALS. CASEY

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: CONSUMER PROTECTION, MEDICAL CARE, FOOD & DRUG REGULATIONS
Control Number: n/a
Copy: SINGLE
Draft Date: 28 FEB 1974
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1974STATE040530
Document Source: CORE
Document Unique ID: 00
Drafter: DHEW/FDA:LRSHELTON
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Film Number: n/a
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1974/newtext/t1974021/aaaaabak.tel
Line Count: 82
Locator: TEXT ON-LINE
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 2
Previous Channel Indicators:
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: STATE 037128
Review Action: RELEASED, APPROVED
Review Authority: WorrelSW
Review Comment: n/a
Review Content Flags:
Review Date: 06 MAR 2002
Review Event:
Review Exemptions: n/a
Review History: RELEASED <06 MAR 2002 by elbezejf>; APPROVED <04 DEC 2002 by WorrelSW>
Review Markings:

Declassified/Released
US Department of State
EO Systematic Review
30 JUN 2005

Review Media Identifier:
Review Referrals: n/a
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
Secure: OPEN
Status: NATIVE
Subject: RECALL OF INTRAVENOUS CATHETER PRODUCTS
TAGS: TBIO, GE, NL, JA, US, FDA, VITAL ASSISTS INC, DESERET PHARM CO
To: BONN TOKYO
Type: TE
Markings: Declassified/Released US Department of State EO Systematic Review 30 JUN 2005